PROPOSED ADDITION
TO
CALIFORNIA CODE OF REGULATIONS
TITLE 16, DIVISION 17

1711. (a) Each pharmacy shall establish and maintain a quality assurance program designed to prevent medication errors.

(b) For purposes of this section, "medication error" means any act or omission in the dispensing process that may cause or lead to patient harm. Medication error, as defined in this section, does not include any act or omission that is corrected prior to furnishing the drug to the patient or patient's agent.

(c) Each quality assurance program shall be described in written policies and procedures maintained in the pharmacy and shall be reviewed by the licensee, and revised if necessary, prior to application for renewal of the pharmacy's license. The policies and procedures shall include directions for communicating the details of the error to the patient, caregiver, prescriber and other members of the health care team as appropriate. This communication shall also describe methods for correcting the error and/or reducing its negative impact on the patient.

(d) Each quality assurance program shall include a process designed to detect and identify medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. If the investigation indicates that the medication error is attributable, in whole or in part, to the pharmacy or its personnel, a quality assurance review shall be performed.

(e) The quality assurance review shall include investigation of the error and completion of an essential cause examination of the error. A written record of the quality assurance review shall be retained in the pharmacy. The written record shall contain at least the following:

1. the date of, location, and participants in the quality assurance review conducted;
2. the record of the facts relating to the medication error;
3. the essential cause examination;
4. the findings and determinations generated by the quality assurance review; and,
5. changes to pharmacy policy or procedure made pursuant to the quality assurance review, if any.
6. Activities undertaken with the patient or other healthcare providers to mitigate the error.

The pharmacy shall inform all pharmacy personnel of any changes in pharmacy policy or procedure made pursuant to a quality assurance review.

(f) For the purposes of this section "essential cause examination" means:

> A process for identifying the basic or causal factors that underlie the occurrence or possible occurrence of a medication error. An essential cause examination focuses primarily on systems and processes, not individual performance. It progresses from special causes in the dispensing process to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines, after analysis, that no such opportunities for improvement exist.

(g) Records relating to activities undertaken as part of a quality assurance review for errors that occurred in the pharmacy, including, but not limited to, investigation or confirmation of a medication error, shall be maintained and immediately accessible in the pharmacy for at least three years from the date those records were created. The board may review quality assurance records in an individual pharmacy as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy.

(h) Neither the proceedings nor records of a pharmacy's quality assurance program shall be subject to discovery in any arbitration, civil, or other proceeding except as provided in subdivision (g). No person in attendance at a meeting of a pharmacy's quality assurance committee shall be required to testify in any arbitration, civil, or other proceeding, except as provided in subsection (g), as to what transpired at that meeting.

(i) The pharmacy's compliance with this section may be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(j) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

(k) This section shall become operative on January 1, 2002.

Note: Authority Cited: Section 4005 of the Business and Professions Code.
Reference Cited: Section 4125 of the Business and Professions Code.